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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/921,635	08/03/2001	James C. Sacchettini	TAMK:247---12740.0247.NP	5795

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09/22/2003

Scott Reese, Ph.D.
Howrey, Simon, Arnold & White, L.L.P.
750 Bering Drive
Houston, TX 77057-2198

EXAMINER

LY, CHEYNE D

ART UNIT

PAPER NUMBER

1631

DATE MAILED: 09/22/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/921,635

Applicant(s)

SACCHETTINI ET AL.

Examiner

Cheyne D Ly

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 August 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-45 is/are pending in the application.
- 4a) Of the above claim(s) 1-16,21,22,31 and 35-45 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 17-20,23-30 and 32-34 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-45 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 6.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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DETAILED ACTION

1. Applicant's election without traversal of Group III, claims 17-34, 3-nitropropionate, compounds selected by design starting from a known inhibitor, and the competitive inhibitor, in Paper No. 9, filed August 01, 2003, is acknowledged.
2. Claims 21, 22, and 31 have been withdrawn due to the elected group not being directed to the elected species.
3. Claims 17-20, 23-30, and 32-34, 3-nitropropionate, compounds selected by design starting from a known inhibitor, and the competitive inhibitor, are examined on the merits.

OBJECTIONS

4. Claims 17, 18, and 20 are objected to due to the inclusion of subject matter, which has been non-elected due to a restriction requirement and therefore, the non-elected subject matter has been withdrawn from consideration.
5. The specification is objected to because of the following informalities: The specification contains figures 4A-4D, however, Figure 4D is not briefly described (page 25). Appropriate correction is required.
6. The title of the invention is not descriptive because the instant title cites a structure and inhibitory agents neither of which are claimed in the elected invention. A new title is required that is clearly indicative of the invention to which the claims are directed.

CLAIM REJECTIONS - 35 U.S.C. § 112, SECOND PARAGRAPH

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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8. Claims 17-20, 23-30, and 32-34 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

9. Specific to claim 17, line 9; 18, lines 9 and 10; 19, line 1, and 20, line 9, the term "non-native" substrate compound causes the claims to be vague and indefinite because it is unclear what criteria are being used to determine that a substrate compound is "non-native" (the substrate compound and microbe are from two different countries or the substrate compound is not naturally occurring within said microbe). Clarification of the metes and bounds of the claims is required. Claims 23-30 and 32-34 are rejected for being dependent from claim 20.

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

12. Claims 17-20, 23-30, and 32-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wilson et al. (US 5,856,116 A) in view of In re Gulack, 703 F.2d 1381, 1385, 217 USPQ 401, 404 (Fed. Cir. 1983) taken with Britton et al. (April 2000) in combination with McKinney et al. (US 6,387,694 B1).

13. Wilson et al. discloses a method for identifying inhibitors having said inhibitor binding to the active site of ICE as defined by the structure coordinates of said ICE (column 8, lines 41-43, lines 51-55, and column 9, lines 20-25), as in instant claims 17-19.

14. The space-filling model of ICE discloses a known inhibitor such as tetrapeptide aldehyde inhibitor bound (contacting) the said ICE (Figures 2 and 4), as in instant claims 20, 23-25.

15. A "competitive inhibitor" is one that inhibits ICE activity by binding to the same kinetic form, of ICE, as its substrate binds (column 5, lines 50-54), as in instant claim 30. Wilson et al. further discloses the limitation of synthesizing inhibitors (column 2, lines 56-61), as in instant claims 29, 32 and 33. It is well known in the art a competitive inhibitor binds to a active and changes the conformation of said active site from open to closed conformation (Campbell, page 107, Figure 6.17).

16. Even though the method disclosed by Wilson et al. does not specify that the atomic coordinates and data directed to Figures 5-7, the specific limitations of atomic coordinates and data directed to Figures 5-7 in this instant case do not distinguish the invention from the prior art in term of patentability because they are descriptive nonfunctional subject matter.

17. In re Gulack defines nonfunctional descriptive material, as when descriptive material is not functionally related to the substrate, the descriptive material will not distinguish the invention from the prior art in term of patentability. Also, the MPEP indicates that descriptive material

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that cannot exhibit any functional interrelationship with the way in which computing processes are performed does not constitute a statutory process, machine, manufacture or composition (MPEP § 2106 (IV)(B)(b)). Specific to the instant case, atomic coordinates and data directed to Figures 5-7 are merely stored so as to be read or outputted by a computer without creating any functional interrelationship, either as part of the stored data or as part of the computing processes performed by the computer, then such descriptive material alone does not impart functionality either to the data as so structured, or to the computer.

18. Britton et al. discloses the crystal structure and active site location of isocitrate lyase from the fungus *Aspergillus nidulans* (Abstract et al.) and nitropropionate and itaconate (second antimicrobial) as inhibitors of ICL from mycobacteria for controlling growth of said mycobacteria (page 350, column 1, lines 1-17), as in instant claims 26, 28, and 34.

19. McKinney et al. discloses the use of the atomic coordinates produced from *M. tuberculosis* isocitrate lyase for identifying ICL inhibitors (column 8, lines 55-66), as in instant claim 27.

20. Willson et al. a method of designing improved enzyme inhibitors. In re Gulack defines nonfunctional descriptive material, as when descriptive material is not functionally related to the substrate, the descriptive material will not distinguish the invention from the prior art in term of patentability. An artisan of ordinary skill in the art would have been motivated to partake the concept emphasized by Wilson et al. and improve on the method by using the method of Wilson et al. for designing inhibitors to isocitrate lyase as taught by Britton et al. and McKinney et al. Therefore, it would have been obvious to one having ordinary skill in the art at the time of the

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invention was made to use the method of designing inhibitors to isocitrate lyase as taught by Wilson et al., Britton et al., and McKinney et al.

CONCLUSION

21. NO CLAIM IS ALLOWED.
22. Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (see 37 CFR § 1.6(d)). The CM1 Fax Center number is either (703) 308-4242 or (703) 305-3014.
23. Any inquiry concerning this communication or earlier communications from the examiner should be directed to C. Dune Ly, whose telephone number is (703) 308-3880. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.
24. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, Ph.D., can be reached on (703) 308-4028.
25. Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instruments Examiner, Tina Plunkett, whose telephone number is (703) 305-3524 or to the Technical Center receptionist whose telephone number is (703) 308-0196.

C. Dune Ly
9/17/03


ARDIN H. MARSCHEL
PRIMARY EXAMINER